

EXHIBIT 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
Food & Drug Adm., CDRH, Att. Marge Hoban
2094 Gaither Road, (Room 007), HFZ-306
Rockville, MD 20850
Phone (301) 594-4695 Fax: (301) 594-4715

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED		PERIOD OF INSPECTION	C.F. NUMBER
TO: Mr. Greg Crane		10/23-26/00	
TITLE OF INDIVIDUAL		TYPE ESTABLISHMENT INSPECTED	
Vice President, International Operations		Medical Device Manufacturer	
FIRM NAME		NAME OF FIRM, BRANCH OR UNIT INSPECTED	
McGhan Médico, S.A.			
STREET ADDRESS		STREET ADDRESS OF PREMISES INSPECTED	
Zona Franca Metropolitana			
CITY AND STATE (Zip Code)		CITY AND STATE (Zip Code)	
Barreal de Heredia, Costa Rica			

DURING AN INSPECTION OF YOUR FIRM IT OBSERVED:

THE OBSERVATIONS NOTED IN THIS FDA-483 ARE NOT AN EXHAUSTIVE LISTING OF OBJECTIONABLE CONDITIONS. UNDER THE LAW, YOUR FIRM IS RESPONSIBLE FOR CONDUCTING INTERNAL SELF-AUDITS TO IDENTIFY AND CORRECT ANY AND ALL VIOLATIONS OF THE GMP REGULATIONS.

1. * The bioburden recovery protocol [] dated [] is deficient in that there is no data to show that the [] rinse were effective.

The first rinse requires agitation on a [] for at [] while the [] rinse require that the test samples be [] for approximately []

* Correction promised by T.S.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	<i>Teresa Jimenez</i>	Teresa Jimenez, Investigator	10/26/00